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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,702	09/15/2003	John Scharf	DMD116	1031
29484	7590	03/27/2006	EXAMINER	
PATENTMETRIX 14252 CULVER DR. BOX 914 IRVINE, CA 92604			BERHANU, ETSUB D	
			ART UNIT	PAPER NUMBER

3735

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,702

Applicant(s)

SCHARF ET AL.

Examiner

Etsub D. Berhanu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/15/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to because Figure 4 is too light and Figures 9 and 10 are too dark to identify elements referenced in the specification. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 110, 500, and 1308. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: elements 800, 1102, 1201, 1204, and 1307. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because lines 8 and 12 contain legal phraseology ("comprises"). Correction is required. See MPEP § 608.01(b).
4. The use of the trademark Velcro has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

5. Claims 16, 44 and 60 are objected to because of the following informalities: the term "comprising" in claims 16 and 44 should be changed to "comprises", and a comma should be inserted in lines 9 and 12 of claim 60 after the term "surface". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 3-5, 9-14, 23, 28, 30-56, and 60-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 3, 5, 23, 31, 33, 51, and 60 is a relative term which renders the claims indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Claims 14, 28, 40 and 56 provide for the use of an apparatus for at least one of a military, sporting, construction, security, policing and firefighting application, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14, 28, 40 and 56 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 30-56 refer to a system, but are dependent on claim 29, which is drawn to a method for monitoring a region of a subject to determine a plurality of physiological characteristics. It is further noted that the limitations of claims 29-56 fail to disclose method steps.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 includes a portion of a dermal layer extending over a chin as part of the claimed subject matter. It is suggested that lines 7-9 of claim 1 be amended to include the phrase “adapted to be/configured to be” to eliminate human tissue as part of the invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-12, 29-40, 57, 58, and 60-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Jobsis et al.'930 (US Patent No. 4,321,930).

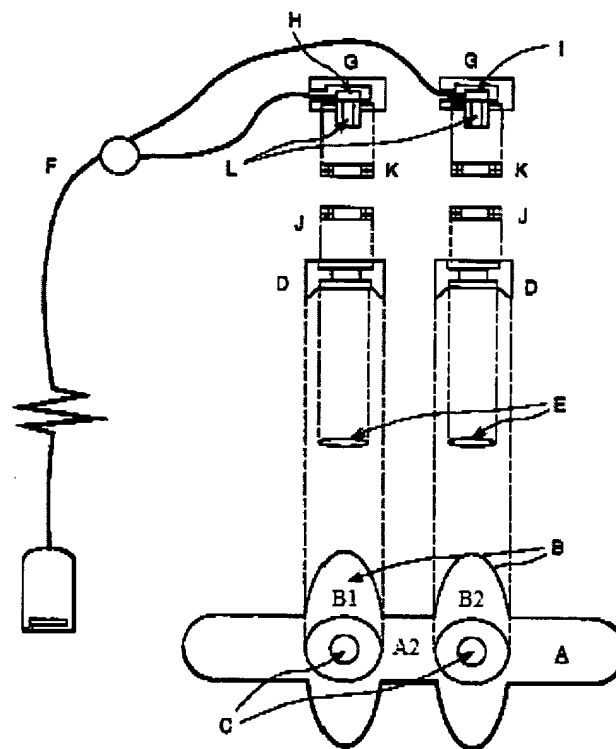
Jobsis et al.'930 discloses a system capable of monitoring the oxygenation state of blood in a tissue (col. 2, lines 59-65) comprising: a reflectance type sensor having a light emitting source and a detector (col. 3, lines 21-27); the sensor further comprising a housing (col. 9, lines 13-23); and an adjustable strap securing the sensor to a region being monitored (col. 9, lines 3-12). Figure 1 discloses the system wherein the light emitting source and detector are positioned in a planar surface and exposed to an external environment, housing 75 has a planar, curved edge region capable of conforming to a contour of a region being monitored (col. 11, lines 27-38), housing 75 is in physical communication with strap 60, and strap 60 is in physical communication with apparatus 65, wherein apparatus 65 is capable of being secured to a head of a subject, and a plurality of straps 60, 61, and 66. Figure 6 indicates a divider 86 between the light emitting source and the detector. It is noted that the system disclosed by Jobsis et al.'930 is capable of being positioned around the chin region of a subject.

12. Claims 1, 15-26, 29, 43-54, 57 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker'868 (US Patent No. 6,144,868).

Parker'868 discloses a pulse oximeter system comprising: a transmission type sensor having a light emitting diode H and a detector I, each having their own housing G (col. 2, lines 45-54), wherein the light emitting diode and the detector are capable of being positioned with a patient's chin juxtaposed in between the diode and detector; securing means comprising an adhesive layer on the detector housing and

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on the light emitting diode housing (col. 3, lines 27-35). Figure 1 of Parker'868, shown below, discloses the system wherein the securing means comprises two separate, adjustable straps, B1 and B2, wherein the first strap B1 is in physical communication with the detector housing when the detector housing is placed in aperture C, and the second strap B2 is in physical communication with the light emitting housing when the light emitting housing is placed in aperture C, and straps B1 and B2 are integrally formed by strap A2, to form apparatus A.

FIGURE 1***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 13, 14, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jobsis et al.'930, as applied to claims 1 and 29, further in view of Wiesmann et al.'550 (US Patent No. 6,199,550).

Jobsis et al.'930 discloses all the elements of the current invention, as discussed in paragraph 11, except for the apparatus being attached to a helmet.

Wiesmann et al.'550 teaches incorporating an oxygen sensor system into an athlete's helmet in order to monitor the exertion of the athlete during competition (col. 15, lines 15-22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Jobsis et al.'930 to be attached to a helmet, as taught by Wiesmann et al.'550, since the helmet would allow the exertion of an athlete during competition to be monitored.

16. Claims 27, 28, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker'868, as applied to claims 1 and 29, further in view of Wiesmann et al.'550 (US Patent No. 6,199,550).

Parker'868 discloses all the elements of the current invention, as discussed in paragraph 12, except for the apparatus being attached to a helmet.

Wiesmann et al.'550 teaches incorporating an oxygen sensor system into an athlete's helmet in order to monitor the exertion of the athlete during competition (col. 15, lines 15-22).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Parker'868 to be attached to a helmet, as taught by Wiesmann et al.'550, since the helmet would allow the exertion of an athlete during competition to be monitored.

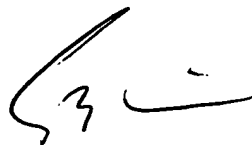
Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571.272.4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDB



ERIC F. WINAKUR
PRIMARY EXAMINER